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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,744	06/18/2001	Rolando Barbucci	1757	3626

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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 10/01/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/830,744

Applicant(s)

BARBUCCI ET AL.

Examiner

Ganapathy Krishnan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: _____

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DETAILED ACTION

Claim Objections

Claims 1 and 3 are objected to because of the following informalities: Claim 2 recites polyacrylic acids as one of the polysaccharides. Polyacrylic acids are not recognized under the classification of polysaccharides. Polyacrylic acids should be removed from Claim 2.

In Claim 3 the notation CMP-J is used within parenthesis for chloromethylpyridylum iodide. Either the notation should be removed or the J in the notation should be replaced with an I for iodide. A comma is missing after p-nitrophenol. The chemical name carbonyltriazole is misspelled. Appropriate correction is required.

Specification

The disclosure is objected to because of the following informalities: The text of the specification is so close to the top of the page, that there are holes punched through the text.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 11 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 3 and 4 of copending Application No 09/830761 ('761). Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 11 of the instant application and Claims 1, 2, 3, and 4 of the copending application ('761) are drawn to polyamine cross-linked polysaccharides containing carboxyl groups.

Claim 11 of the instant application is drawn to cross linked polysaccharides obtainable by the process of Claim 4, which is multiply dependent on Claim 2, and Claim 1. One of the polysaccharides used in the process of cross linking is selected from a group which has hyaluronic acid listed as one of the members (instant claim 2). The cross linked polysaccharide of instant Claim 11 is obtained by cross linking with polyamines of instant Claim 4. The polyamine of instant Claim 4 is same as the ones used in Claim 3 and Claim 4 of the copending ('761) application. Both hyaluronic acids of Claim 1 of the copending ('761) application and the polysaccharides of the instant application have carboxy groups. The only difference is that, the cross linked polysaccharide of instant Claim 11 is obtained by first activating the carboxy group and then cross linking with the polyamine, whereas no such activation of the carboxy group is recited in Claims 1-4 of the copending ('761) application.

One of ordinary skill in the art would readily acknowledge the overlap in subject matter between instant Claim 11 and conflicting Claims 1-4 of the copending application ('761).

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Indeed, to ultimately issue claims to both applications at different times would cause the unjustified and improper timewise extension of the right to exclude granted by a patent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 4 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites, 'obtained from tissues or bacteria' within parenthesis. It is not clear if the applicants intend this limitation to be part of the claim or not. If it is intended to be part of the claim, the parenthesis should be removed.

Claim 4 recites the terms 'hetaryl group'. It is not clear what hetaryl group means. If the applicants mean a heteroaryl group, the term should be amended to reflect the proper term 'heteroaryl'.

JOINT INVENTORS

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Della Valle et al (USPN 5,676,964) in combination with Qin (EP 0566118) and Conti et al (USPN 4,810,695).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-11 are drawn to a process for the preparation of cross-linked polysaccharides containing carboxy groups comprising activation of the carboxy group of the polysaccharide by a carboxy activating group and reacting the polysaccharide with a polyamine; various

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carboxypolysaccharides; carboxy activating agents; polyamines with different substitutions as cross-linking agents; salification of the polysaccharide with a lipophilic cations like tributyl or tetra alkyl ammonium ions; solvent for carrying out the cross-linking reaction; sulfation of the cross-linked polysaccharide with pyridine/sulfur trioxide complex; complexation of the cross-linked further with copper, iron or zinc ions and the cross-linked polysaccharide obtainable by the process.

Della Valle et al teach the cross-linking of carboxy polysaccharides in which an ester is formed via inter and intra molecular cross-linking of an activated carboxy group with a hydroxy group (see col. 1, summary and col. 1, lines 62 through col. 2, line 3). The carboxy groups to be converted are activated starting from the polysaccharides containing free carboxy groups or from salified carboxy groups for example with salts such as quaternary ammonium salts (see col. 2, lines 42-64 and col. 4, lines 56-67)). The carboxy group is also activated by forming esters such as p-nitrophenyl esters (see col. 3 lines 1-30). Another example of a reagent that is useful for the activation of the carboxy group is 2-chloro-N-methyl-pyridinium chloride (see col. 4 lines 16-19), which though not the same as chloromethylpyridylium iodide of instant claim 3, is similar. The reactions can be carried out in dimethyl or diethyl formamide (see col. 4, lines 29-32).

However Della Vale et al do not teach the crosslinking of activated carboxy groups using a polyamine, sulfation of the crosslinked polysaccharide with pyridine/sulfur trioxide, complexation of the crosslinked polysaccharide with copper, zinc and iron ions.

Qin teaches the crosslinking of carboxyalkyl celluloses using diamines and polyamines (see page 4 lines 12-30). Specific example provided is the crosslinking of carboxymethyl

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cellulose with diethylene triamine (see page 8, example 1 and page 10, Table 1, sample nos. 47 and 48).

Conti et al teach the sulfation and the complexation of chitosan with ferrous ions. The sulfation is carried out in dimethylformamide at a temperature of between 0°C and 2°C for 20-60 minutes using sulfur trioxide and pyridine (see col. 2, lines 1-33). Even though Conti teaches the complexation with iron and sulfation of chitosan, both these reactions can be carried out on a crosslinked polysaccharide. The complexation with copper and zinc can be carried out in a similar manner and is within the purview of the skilled artisan.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the carboxy group activation taught by Della Valle et al with the crosslinking of carboxymethyl cellulose with diamines taught by Qin, in a process to make crosslinked polysaccharides containing carboxy groups by first activating the carboxy group and then performing the crosslinking via a diamine or a polyamine and further sulfating and complexing with metal ions using the teachings of Conti, with reasonable amount of success, since the process steps are seen to be disclosed in the prior art.

One of ordinary skill in the art would have been motivated to do so since the process may lead to crosslinked polysaccharides with enhanced gelation ability which are needed for use in cosmetic and industrial applications and also medical applications where controlled metal ion release is needed. The metal ion complexing ability of these crosslinked polymers could also find wide environmental applications.

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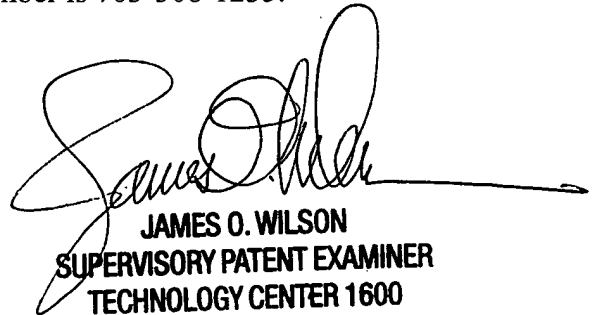
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 703-305-4837.

The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

GK
September 27, 2002



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600